

Evaluation of the Buprenorphine Waiver Program

Results from SAMHSA/CSAT's Evaluation of the
Buprenorphine Waiver Program
The College on Problems of Drug Dependence
June 20, 2005

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Key Goals of the Evaluation

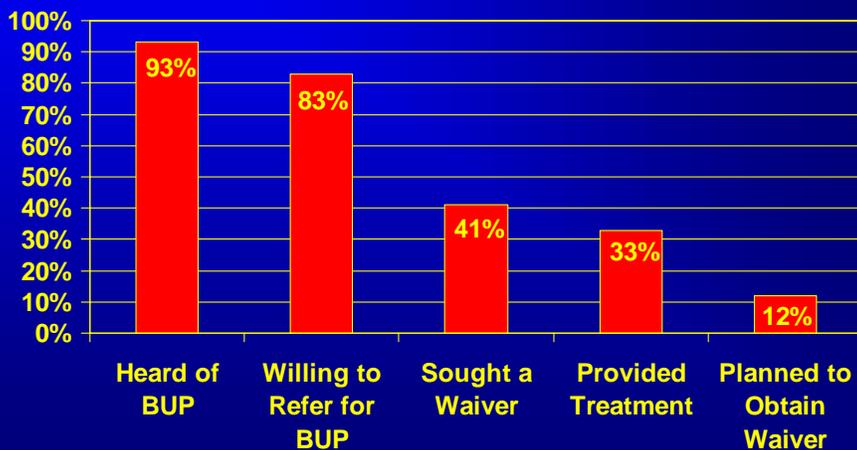
Per the supporting legislation, describe the impact of the Waiver program upon:

- **AVAILABILITY** of detoxification and maintenance treatments;
- **EFFECTIVENESS** of these treatments; and
- Potential adverse **PUBLIC HEALTH CONSEQUENCES**, including **DIVERSION** activities.

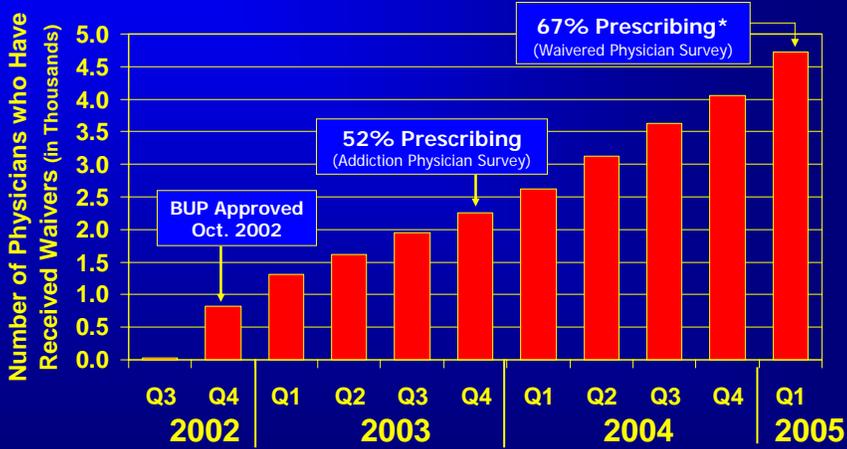
Data Collection Activities

- **Addiction Physician Survey**
(Fall 2003)
- **Longitudinal Patient Study**
(April 2004 – June 2005)
- **Waivered Physician Survey**
(Winter 2005)

Addiction Physicians are Aware of Buprenorphine (2003)

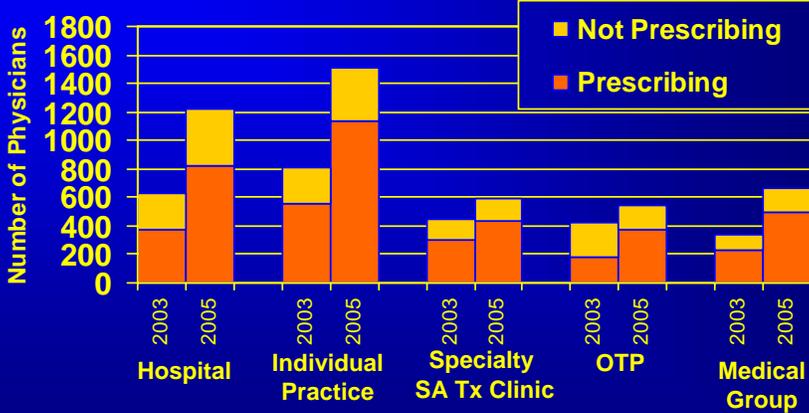


Number of Waivered Physicians Estimated Number Prescribing



* An estimated 2,353 physicians were providing treatment under the Waiver Program in early 2005

Practice Setting of Waivered Physicians

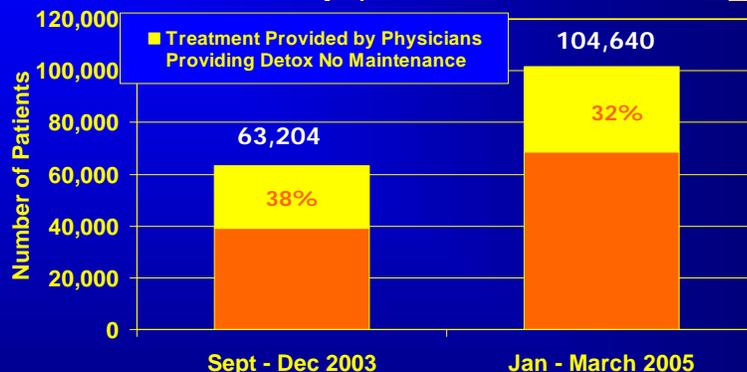


40% and 43% of the sample work in more than one practice setting in 2003 and 2005 respectively

Practice Setting

2003 data are from the Addiction Physician Survey, 2005 data are from the Waivered Physician Survey

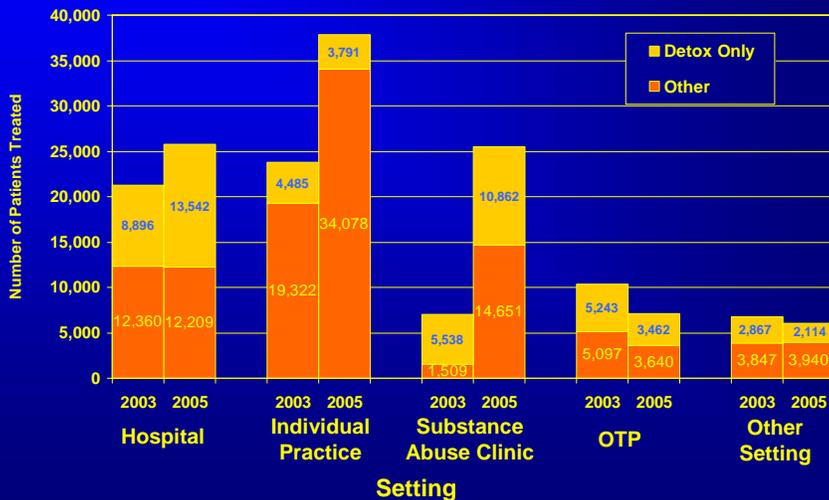
Cumulative Estimate of Number of Patients Inducted



Mean # of Patients/Physician	57	46
SD	6	147
Range	1-800	1-1011

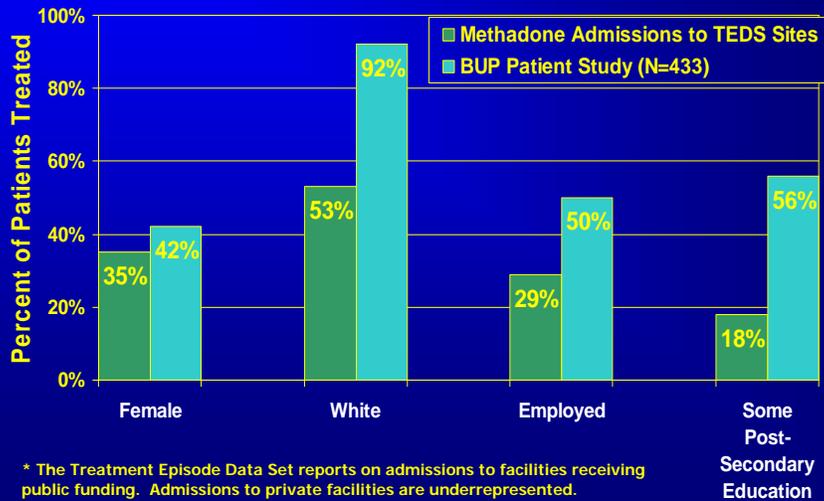
2003 data are from the Addiction Physician Survey, 2005 data are from the Waivered Physician Survey

Patients Inducted by Setting & Treatment Offered

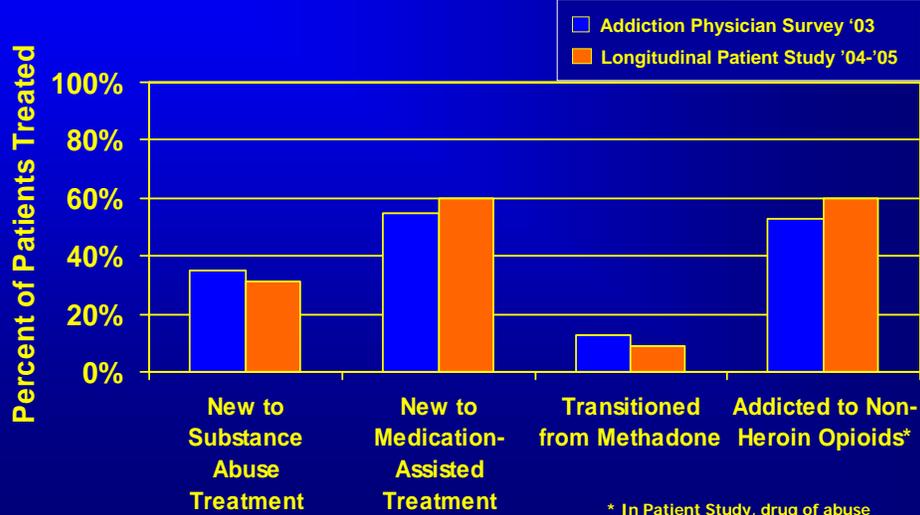


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Methadone Patients* & BUP Patient Study Sample: Demographic Differences

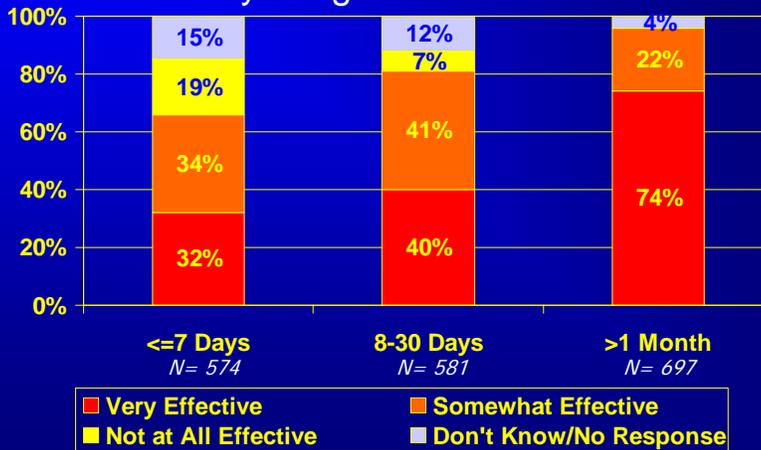


Characteristics of Patients Treated Under the Waiver Program



Prescribing Physicians* Perceptions of BUP Effectiveness

By Length of Treatment



*Views reported by physicians who also reported experience treating for that length of time

Top Challenges Reported by BUP PRESCRIBERS

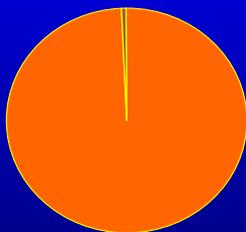
- Most challenging aspects of providing BUP treatment:
 - Patients' inability to pay for treatment/medication (49%)
 - Patients' resistance to required substance abuse counseling (42%)
 - Treating concurrent nonopioid substance abuse (35%)
- Factors that prescribers say decreases the number of patients treated:
 - 30-patient limit (32%)
 - Few referrals or appropriate patients (27%)
 - Patients' resistance to required substance abuse counseling (24%)
 - Poor patient compliance/retention (20%)

Top Barriers Reported by NON-PRESCRIBERS

- **Reasons for not prescribing:**
 - Difficult logistics (e.g., office setup, recordkeeping) (39%)
 - Few referrals or appropriate patients (30%)
 - Patients' inability to pay for treatment/medication (23%)
- **Why seemingly appropriate patients refused BUP treatment:**
 - Medication too expensive (42%)
 - Office visits too expensive (26%)
 - Unknown as patient did not follow through (23%)
 - Chose methadone program instead (20%)

Severe Adverse Reactions to BUP Treatment Relatively Rare

**Physicians Report .5%
of Patients
Experienced Severe
Adverse Rx**



- **Specific reactions reported (unweighted):**
 - Withdrawal: 103
 - Allergic reactions: 12
 - Respiratory depression: 9
 - Drug interactions: 9
 - Liver problems: 2
 - Renal insufficiency (or aggravation of it): 2
 - Unspecified: 80

Physicians reported 217 patients with adverse reactions, out of a total 47,664 patients inducted (unweighted).

Summary of Findings

- Proportion of Waivered physicians who prescribe is increasing
- Modest increase in number of patients inducted
- Patients treated with BUP at this time may represent a subpopulation different from that treated in OTPs, perhaps due to cost factors
- Physicians report BUP treatment more effective when prescribed longer than one month
- Few adverse reactions
- Physicians attempting to provide BUP treatment face multiple challenges, with cost remaining an ongoing issue

Evaluation of the Buprenorphine Waiver Program: Contacts

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Evaluation overview available at www.buprenorphine.samhsa.gov

30-day outcomes for buprenorphine patients treated by a national sample of qualified physicians

Findings from CSAT's Evaluation of the Buprenorphine Waiver Program

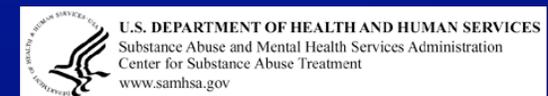


Poster Presented at
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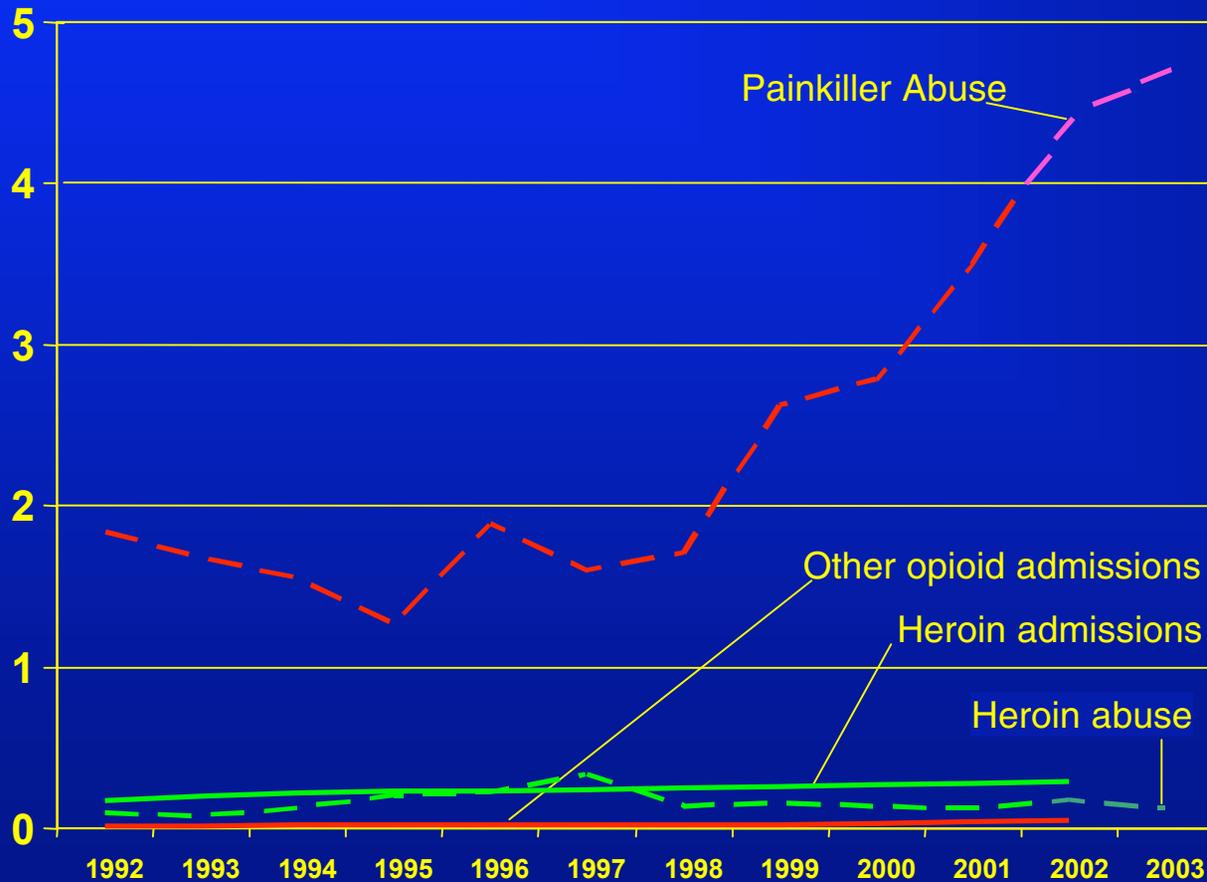
¹ Westat, Rockville, MD

² Substance Abuse and Mental Health Services Administration,
Center for Substance Abuse Treatment, Rockville MD



The Gap Between Abuse & Treatment of Painkillers (Non-heroin Opioids) is Large and Has Grown Over Time

Reporting Abuse or # Admissions (in Millions)



National abuse statistics are provided by the National Household Survey on Drug Abuse (NHSDA), reporting on painkiller abuse and heroin abuse. Abuse is reported, not dependence. Discontinuity of trends begins at 2002 with the beginning of the National Survey on Drug Use and Health (NSDUH).

Treatment statistics are provided by the Treatment Episode Data Set (TEDS). TEDS reports on the number of admissions, rather than the number of individuals treated for heroin and non-heroin opioids as the primary, secondary, or tertiary drug of abuse. TEDS obtains information primarily from sites receiving public funding, so private facilities are underrepresented in this chart.

Drug Addiction Treatment Act of 2000 (DATA)

- Establishes a program of waivers that permit qualified physicians to **dispense or prescribe from a range of healthcare settings** narcotic drugs approved by the Food and Drug Administration (FDA) for the treatment of addiction to opiates.
- **Buprenorphine (BUP) is the first medication** to be distributed under the Waiver program.
- DATA also specifies that the Secretary of the Department of Health and Human Services (HHS), in conjunction with the Attorney General, may make determinations concerning whether:
 - treatments provided under the Waiver have been **effective** forms of maintenance and detoxification treatment in clinical settings;
 - the Waiver has significantly **increased the availability** of maintenance treatment and detoxification treatment; and
 - such Waivers have **adverse consequences for the public health**.

Key Goals of the Evaluation



Per the supporting legislation, describe the impact of the Waiver program upon:

- **AVAILABILITY** of detoxification and maintenance treatments;
- **EFFECTIVENESS** of these treatments; and
- Potential adverse **PUBLIC HEALTH CONSEQUENCES**, including **DIVERSION** activities.

Purpose

To describe the characteristics of and track outcomes for a representative sample of patients treated under the Waiver Program

Procedures

Site Selection

- Drew random stratified sample of 400 physicians from CSAT's Buprenorphine Waiver Notification System in April 2004
- Physician/sites eligible to participate if prescribing; 67% reported that they were prescribing BUP
- 123 sites qualified and were willing to participate (46% of prescribing physicians)
- Due to slow flow of new patients through sites, also included purposive sample of 9 induction centers
 - Induction centers specialize in induction of patient onto BUP
 - After induction, patient transferred to other Waivered physician for maintenance

Patient Recruitment

- Patient recruitment brochures mailed to each site had a unique ID number
- Brochures consisted of 2 sections separated by perforation:
 - Staff gave new patients one section with a toll-free telephone number, description of the study, and an ID number
 - Staff completed the second section with a checklist of observable patient demographic characteristics and mailed it to Westat
- Patients called Westat for interview at initiation of treatment, with follow-up telephone interviews at 30 days and 6 months
- Telephone interviewers accepted interviews only from persons with valid ID numbers
- Number of nonresponders determined by number of cards returned without accompanying interview
- Participants received an incentive for each completed survey: \$40 for baseline, \$50 for 30 day followup, and \$60 for 6 month follow-up

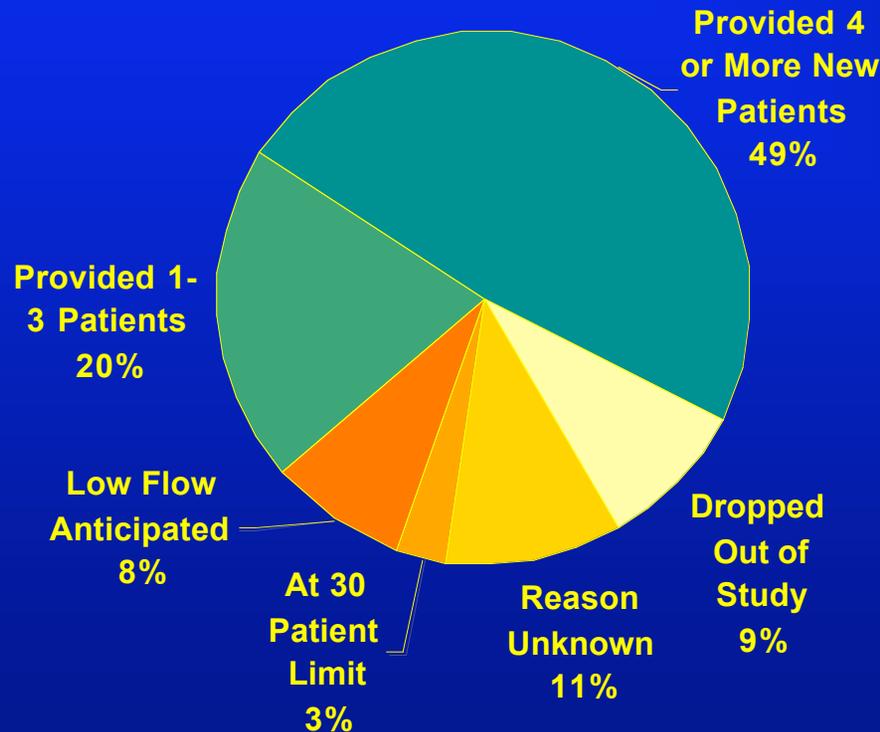
- All instruments and procedures were reviewed and approved by Westat's Institutional Review Board and by the Office of Management and Budget

Participation, Recruitment, and Followup Rates

- 46% of prescribing physicians agreed to participate
- 43% of 1,000 patients initiating treatment provided interviews
 - No systematic recruitment bias with respect to age group, race, or ethnicity
 - Women more likely to provide interviews than men
 - Enrolled sample was 42% female, but only 37% of those initiating treatment were female ($p < .05$)
- Follow-up rate at 30 days was 95%
- Although the goal was to obtain a nationally representative sample of patients treated under the Waiver Program, the sample was self-selected to some extent (as expected). Nevertheless, the trends identified in these data are the best available indications of trends in sites providing buprenorphine across the U.S.

Patient Flow Was Limited by Demand & by the 30-Patient Limit

Number of Patients Provided by Participating Sites



Patient demand may be low, at least in some parts of the U.S.

- Of the 132 participating sites, 31% reported no new patients during the study period.
- Only 3% of sites reported no new patients due to the 30-patient limit.
- 8% did not expect many new patients from the outset of the study.
- 9% dropped out of the study because physician changed their minds about participating, stopped prescribing, or left the location and could not be located.

Characteristics of Respondents in Patient Study

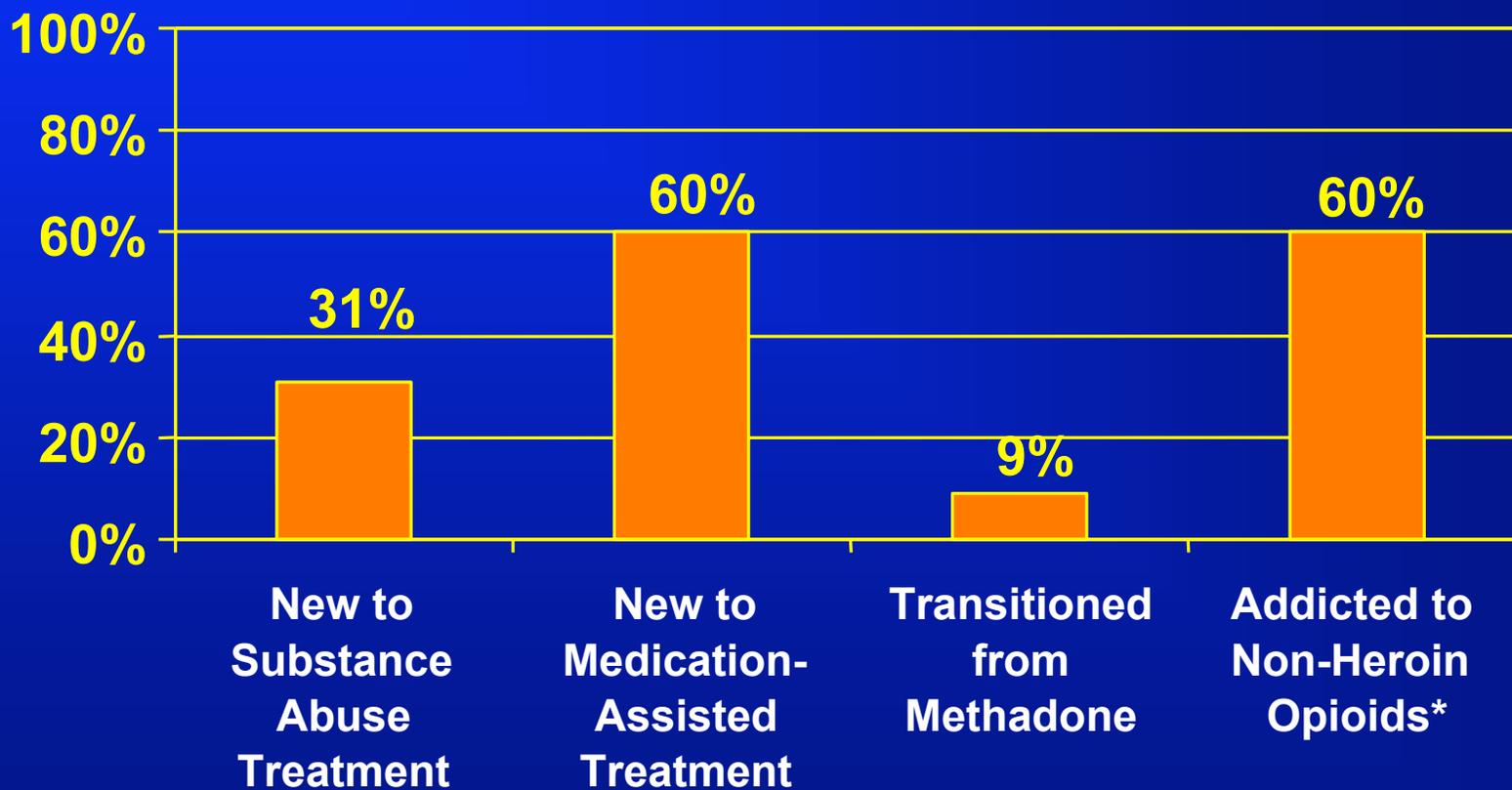


The sample is:

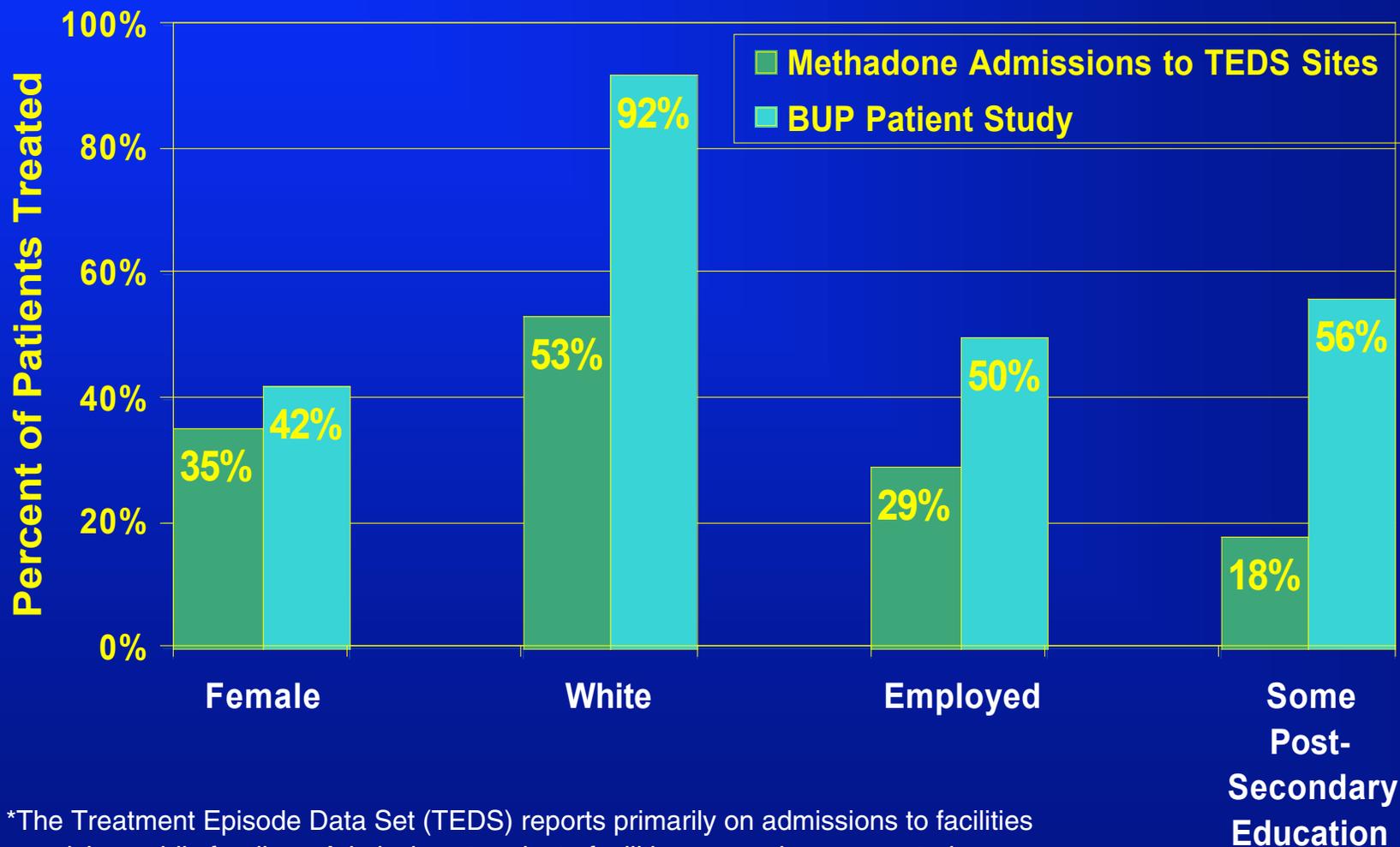
- 58% male
- 92% white
- 50% working full or part time
- 56% with at least some college experience
- 46% with household income above \$35,000
- Mean age 36.9 (SD 11.5)
- 59% primary opioid in 30 days prior to treatment was NOT heroin

Characteristics of Respondents in BUP Patient Study

Percent of Patients Treated

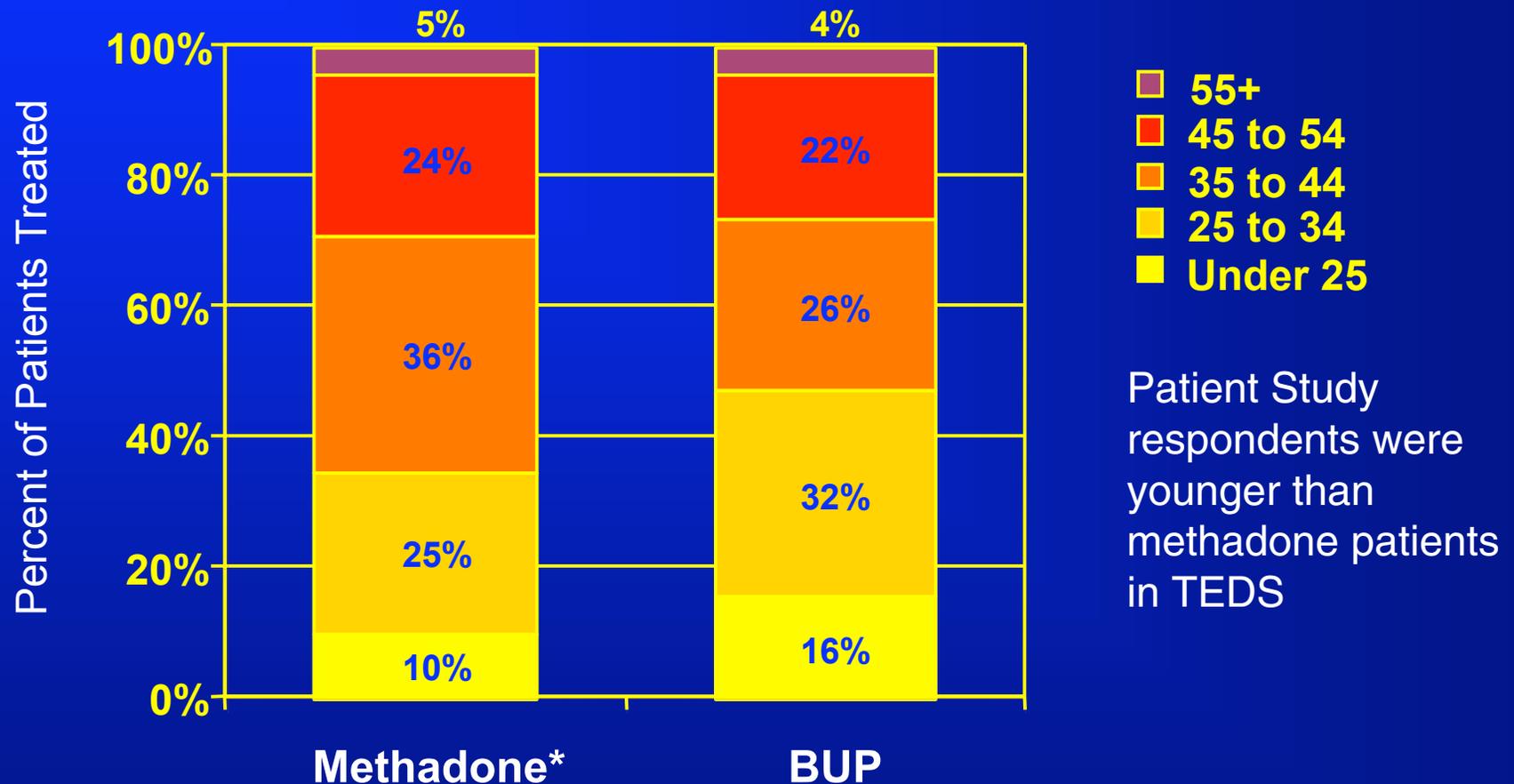


Methadone Patients* & BUP Patient Study Sample: Demographic Differences



*The Treatment Episode Data Set (TEDS) reports primarily on admissions to facilities receiving public funding. Admissions to private facilities are underrepresented.

Methadone Patients* & BUP Patient Study Sample: Age Differences



Patient Study respondents were younger than methadone patients in TEDS

* Patients admitted for methadone treatment in sites reporting to TEDS, thought to primarily reflect publicly funded facilities

Primary Opioid of Abuse in 30 Days Prior to Treatment

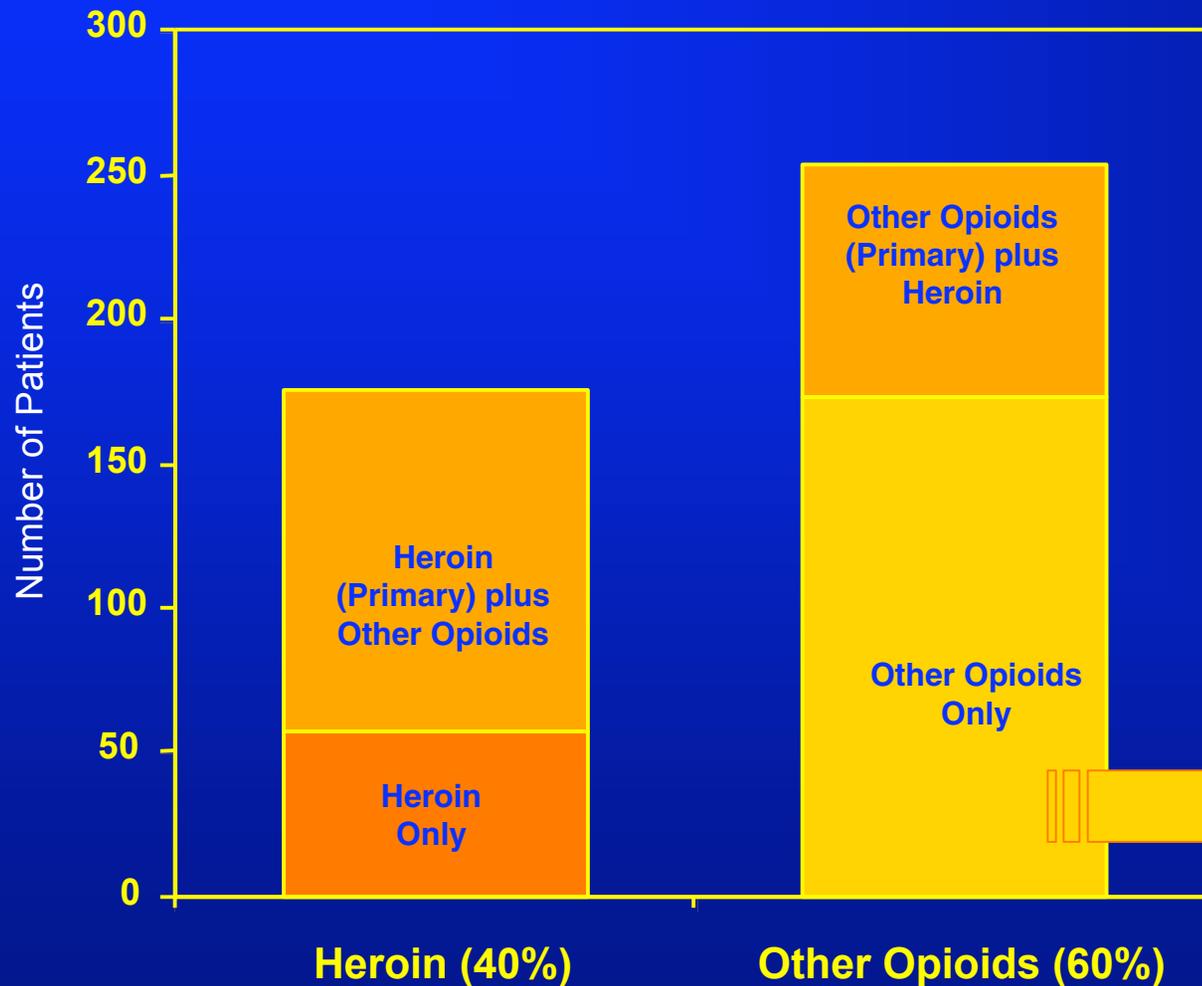
<u>Primary Opioid of Use*</u>	<u>Frequency</u>	<u>% Sample</u>
Heroin	174	40%
Oxycodone	124	29%
Hydrocodone	74	17%
Street Methadone	18	4%
Multiple Rx Meds	10	2%
Hydromorphone	9	2%
None Specified	8	2%
Morphine	5	1%
Rx Methadone	4	1%
Fentanyl	3	1%
Other	5	1%

60% reported primarily using opioids other than heroin in the 30 days prior to treatment.

*The primary drug of abuse was determined by an item asking for the opioid used most often in the last 30 days. The primary drug of abuse for 9% of the sample in a controlled environment such as jail or inpatient treatment in the 30 days prior to treatment was determined by the drug with the longest lifetime use.

Other = Propoxyphene, Meperidine, Tramadol, Codeine, Opium

Primary Opioid Abused & Regular Problematic Use of Other Opioids



Of those reporting heroin as the primary drug of abuse, 66% also reported regular abuse of other opioids for at least one month.

Of those reporting other opioids as the primary drug of abuse, only 32% also reported the regular abuse of heroin for at least one month.

There is evidence that individuals with abuse limited to non-heroin opioids represent a distinct patient subpopulation.

40% of the sample limit their abuse to non-heroin opioids.

Primary Opioid Abused 30 Days Prior

Differences Between Heroin Users & Individuals Limiting Abuse to Oxycodone

The National Survey on Drug Use and Health reports:

- Individuals abusing oxycodone only over their lifetime are more likely to be:
 - female (43.7%)
 - younger (age 12 to 34)than either heroin-only users or heroin and oxycodone users
- Compared to oxycodone-only abusers, heroin-only abusers are more likely to report:
 - lower family income
 - being black (26.8%) and/or some other races/ethnicities (7.5%)
- **Patients abusing oxycodone represent the highest proportion of non-heroin users in our Patient Study sample**

Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *National Survey on Drug Use and Health Report: Nonmedical oxycodone users: A comparison with heroin users.* January 21 2005.

BUP Patients Abusing Only Non-heroin Opioids Differ from Other Opioid Abuse Groups

	Heroin Only N=59	Non-heroin Opioids Only N=173	Heroin & Non- heroin Opioids N=198
Female*	31%	50%	38%
White*	69%	98%	93%
Some college	51%	62%	54%
Working+	49%	56%	44%
Age 18-34*	34%	41%	58%
Household Income Greater Than \$75K*	5%	31%	13%
Court Involved*	23%	15%	36%

* Statistically significant at $p < .01$

+ Statistically significant at $p < .10$

BUP Patients Abusing Only Non-heroin Opioids Have Different Treatment Histories Than Other Opioid Abuse Groups

	Heroin Only N=59	Non-heroin Opioid Only N=173	Heroin & Non-heroin Opioids N=198
New to Drug Abuse Treatment*	25%	48%	20%
New to Medication-Assisted Treatment*	46%	75%	50%
Transitioned From Methadone	8%	6%	12%

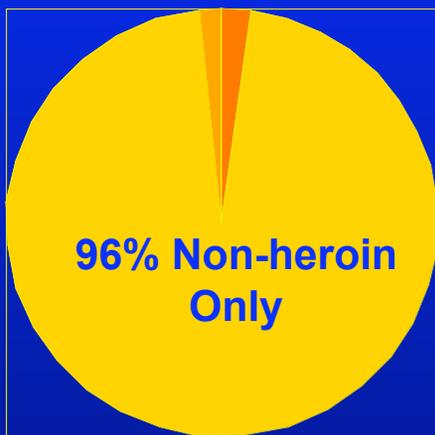
* Statistically significant at $p < .01$

+ Statistically significant at $p < .10$

Discrepancy Between Populations Abusing Opioids & Population Treated

Opioid Abuse

NSDUH Past Month Use 2002



4,549,570 reported opioid abuse

Methadone Treatment

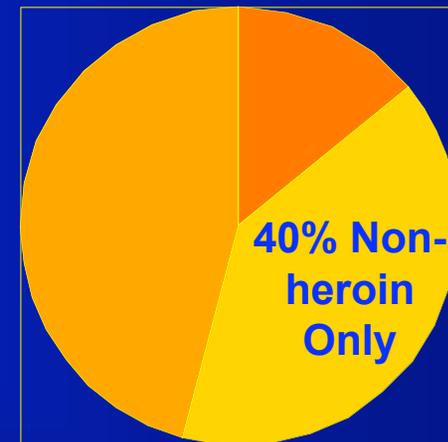
TEDS 2002 Admissions Involving Methadone Treatment



111,885 admissions involved methadone treatment

Treatment Under the Waiver (BUP)

Patient Study BUP Evaluation 2005



434 patients recruited from 132 sites

■ Heroin Only

■ Non-heroin Opioids Only

■ Heroin & Non-heroin Opioids

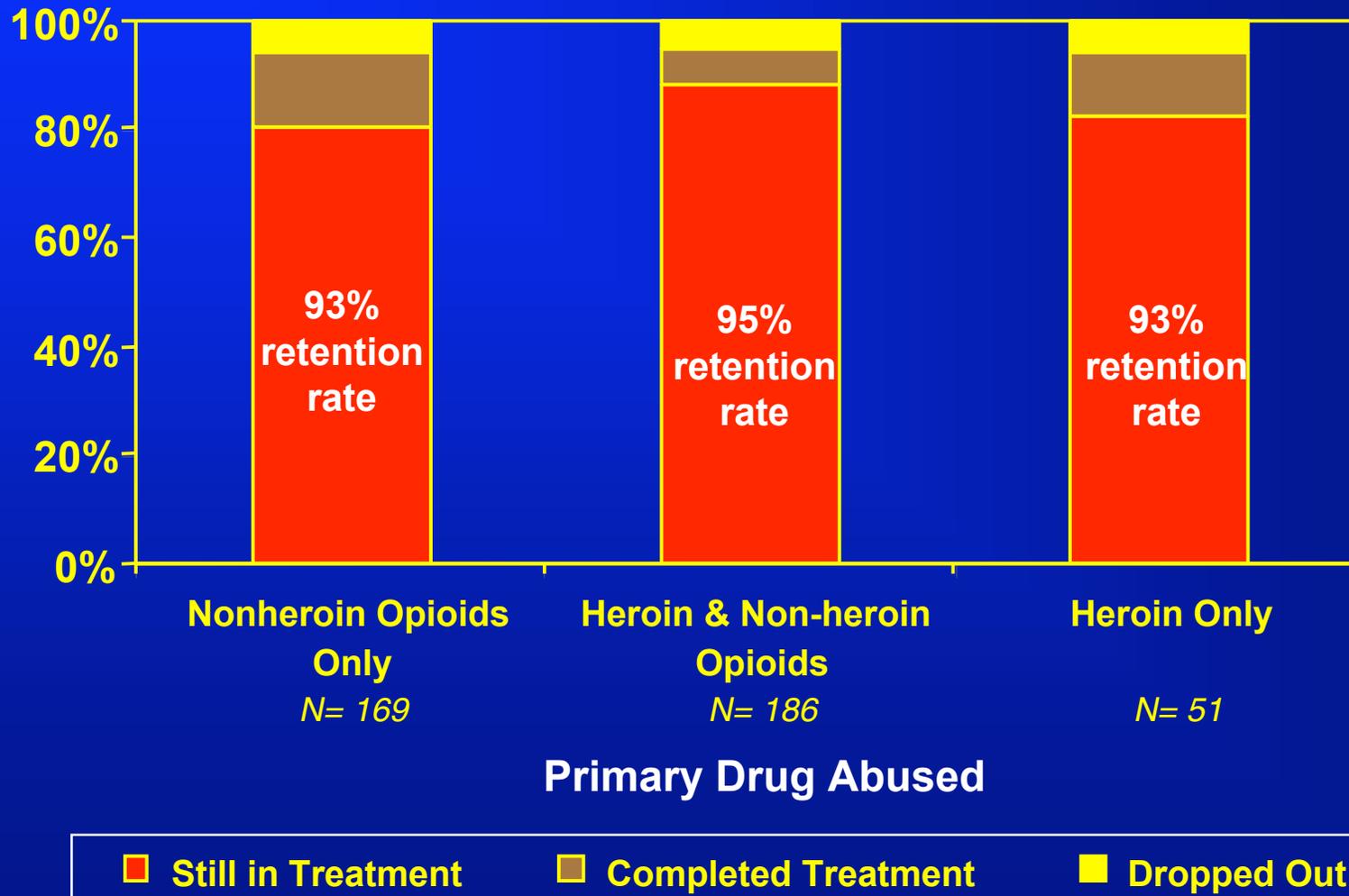
30 Day Outcomes

- 95% followup rate for sample as a whole
- Patients abusing heroin only more likely to be lost to followup

	Heroin Only N=59	Non-heroin Opioid Only N=173	Heroin & Non-heroin Opioids N=198
Followup at 30 Days	86%	98%	95%

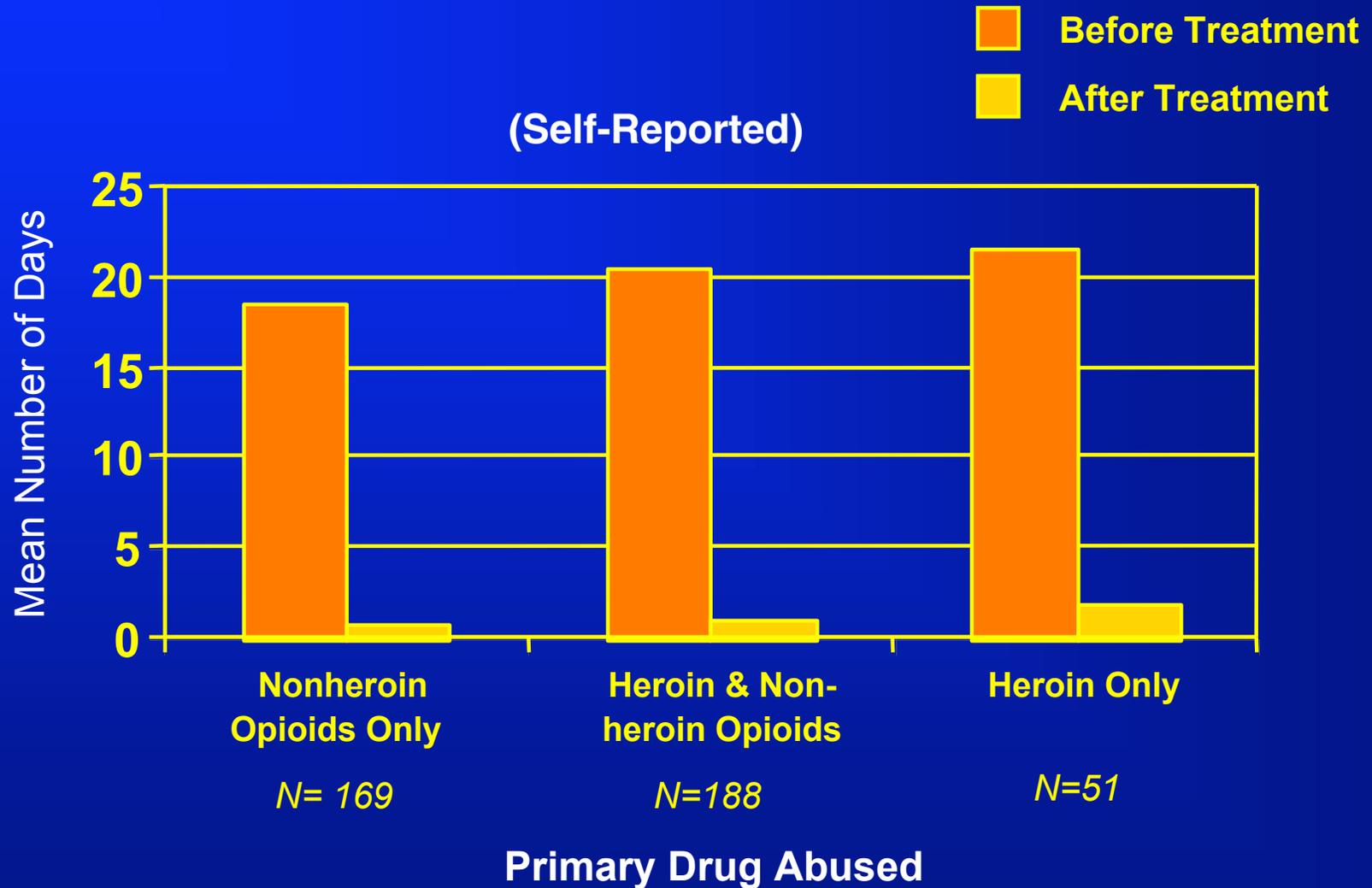
30 Day BUP Treatment Outcomes: Treatment Retention at 30 Days

(Self-Reported)



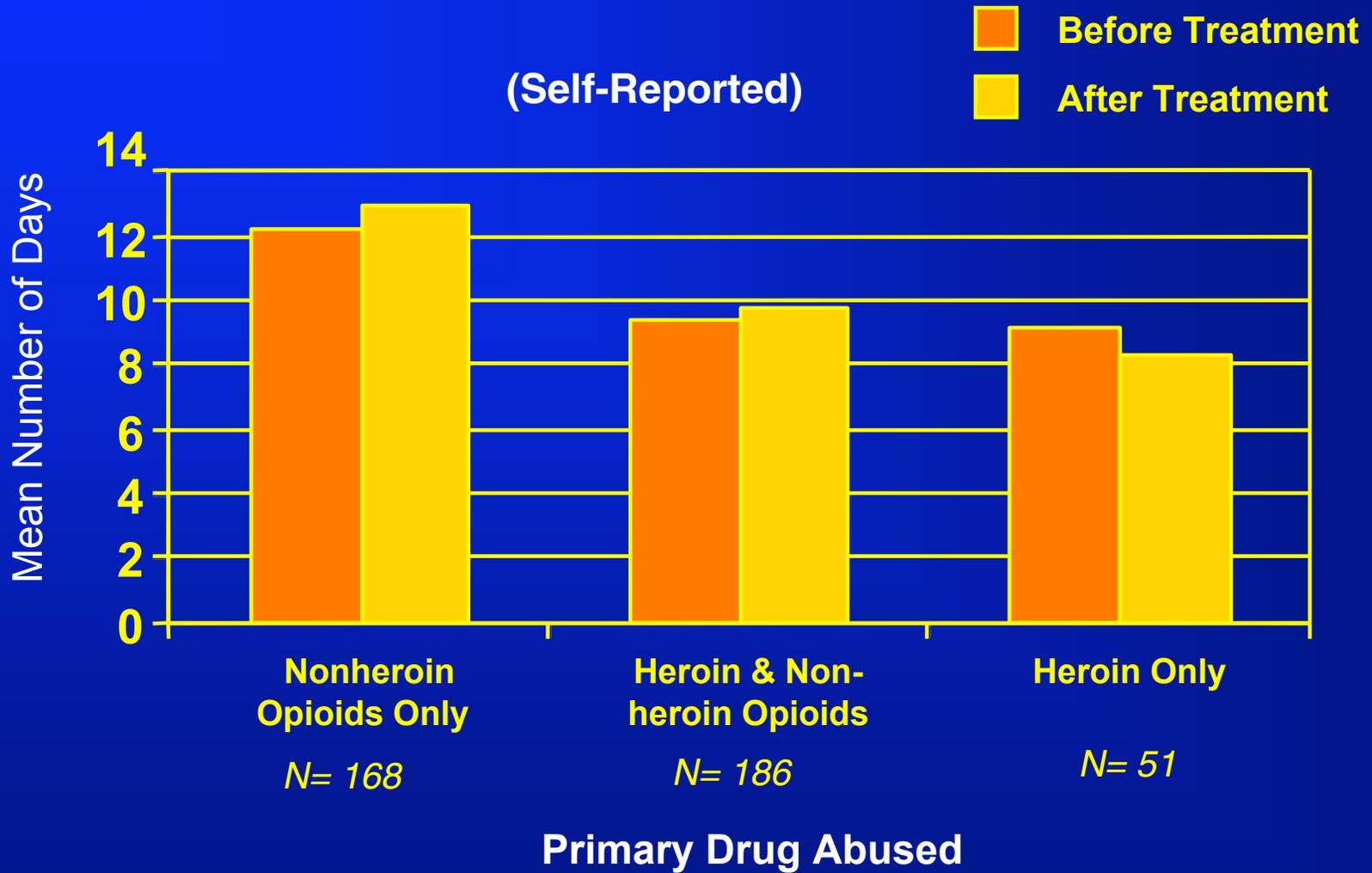
Excludes 22 lost to followup

30 Day BUP Treatment Outcomes: Past 30 Day Use of Opioids



Excludes 22 lost to followup

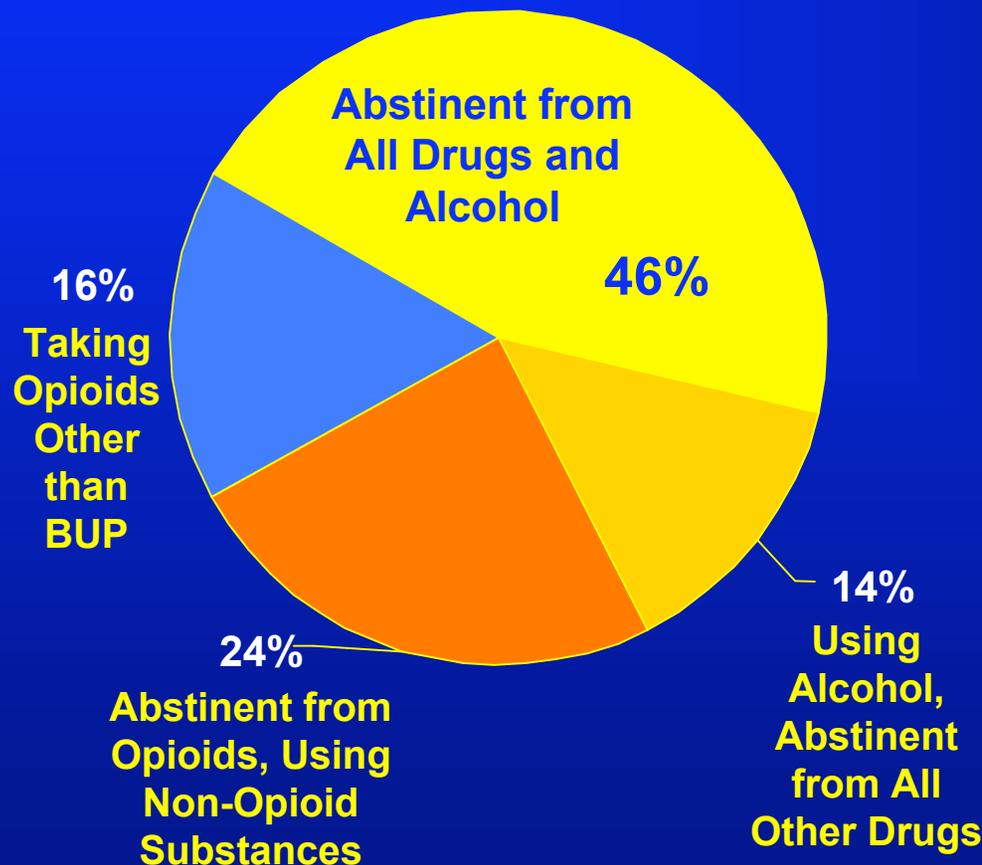
30 Day BUP Treatment Outcomes: Mean Days Worked in Past 30



Excludes 22 lost to followup

30 Day BUP Treatment Outcomes: Abstinence from Drugs

(Self-Reported)



N= 411

46% Abstinent from Alcohol and All Other Drugs

84% Abstinent from Opioids Other than BUP

Excludes 22 lost to followup

Patient Study Summary



- Few new patients moved through study sites May '04 – Feb '05
- BUP treatment may be attracting a subpopulation more likely to be white, female, and more affluent than subpopulations treated through methadone clinics reporting to TEDS
- A high proportion of patients treated with BUP appear to be addicted to non-heroin opioids, such as painkillers
- BUP treatment appears to be effective at 30 days in terms of retention in treatment, use of opioids other than BUP, and abstinence from AOD
- BUP treatment has less of an effect on employment at 30 days, but the period may be too short for treatment to have an effect
- Though literature suggests that heroin users have lower treatment success rates than other opioid users, there are no significant differences in effectiveness at 30 days in this BUP study

Conclusion



- Early in the dissemination of BUP treatment, it appears as if many patients treated under the Waiver are more affluent and likely to be white than patients treated in methadone programs. This may change as treatment becomes more available.
- Outcomes at 30 days appear promising; analysis of 6-month followup data currently being collected will provide a more complete picture of treatment effectiveness.

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